EXHIBIT R

From: Cameron, Roger
To: "Ben Watson"; christy.jones@butlersnow.com; "dbthomas@agmtlaw.com"
Cc: Tom P. Cartmell; Andrew N. Faes; "Bryan Aylstock"; Renee Baggett
Bcc: Balefsky, Lee; Dehadrai, Jai
Subject: RE: Requesting Due Diligence Documents
Date: Monday, November 04, 2013 12:54:03 PM

Dear Ben:

Please note that, after careful review of the productions to date, we require that you produce the following documents and reserve the right assert that these documents are already the subject of outstanding Requests for Production. Please reply whether they are lost or not. Be advised that if you do not respond within one week of this request, we will be obliged to put this request on the docket with Judge Eifert.

1. PR563-001 Release Authorization for Prolene for use as a hernia mesh or as a pelvic floor implantation a/k/a IVS and/or TVT between 1990 and 2002;

2. All Clinical Evaluation Reports submitted as required by EC Directive 93/42/EEC, 14 June 1993 to obtain CE mark authorization for Medscand and/or Ethicon for the IVS and/or TVT products;

3. All Risk Analyses and/or Risk Management Reports, whether denominated as such or as a DDSA, aFMEA, pFMEA, dFMEA or otherwise, for the IVS and/or TVT products, including but not limited to the following: Analysis made 1998-09-22 by Margareta Eriksson and Tommy Svensson (Preventia AB), system description, attached drawings; Review of analysis 1999-01-27 by Margareta Eriksson and Tommy Svensson (Preventia AB) (Revised TVT-2 device: 5 mm needle, shiny surface, tip angle same as 6 mm; transparent shrink tube, packed in double plastic, handle screw instead of O-ring); Utgava 3 (undated); Utgava 4 1999-06-01 (Genomgang av ME/TS); Utgava 5 1999-06-23 (Ny vardering av risker TS/ME); Review of Risk analysis based surveillance data and complaint statistics 1999 (performed by ME and TS 2002-02-02);

4. All reports and underlying data on elongation tests, including but not limited to bi-directional elasticity tests, performed on 6 mil construction Prolene by or on behalf Ulf Ulmsten, Medscand and Ethicon between 1990 and 2002;

5. All documents that constitute, refer or relate to any IDE that defendants prepared and/or obtained to provide Prolene mesh to Ulf Ulmsten, any hospital with which he was affiliated, Medscand or any other person between 1990 and 2002;

6. All Essential Requirements Checklists and supporting document prepared by defendants, Medscand and/or anyone acting on their behalf;

7. Any notes, handwritten or electronic, made before, during or after by any member of the due diligence teams for the License and Supply Agreement or the Asset Purchase Agreement that refer or relate to the due diligence performed or approved with respect to those agreements;

8. All documents that MedScand submitted to any Notified Body, including but not limited to the Danish Notified Body, for the purpose of obtaining a Declaration of Conformity and/or the right to affix the CE Mark to Medscands' IVS and/or TVT product;

9. Any documents that Ethicon, Inc., Ethicon Scotland or any J&J entity prepared for its own submission of for anyone else's submission to any Notified Body, including but not limited to the Danish Notified Body, for the purpose of obtaining a Declaration of Conformity and/or the right to affix to the CE Mark to Medscand's IVS and/or TVT Product or any of the manufacturing and development processes related to them.

10. The complete Design History File by Medscand, including but not limited to any documents that singly constituted only a part of the contents of the Design History File and/or Technical File, in Swedish for the IVS and/or the TVT that was made available to the Acquisition Due Diligence Team and/or submitted to the Danish Notified Body;

11. The English and French translations of that Design History File and/or its constituent parts;

12. All specifications for the IVS and/or TVT products and system components in effect at Medscand when Ethicon entered into negotiations with Medscand which culminated in the parties' License and Supply Agreement;

13. All documents that constitute, refer or relate to any agreement between Ulmsten and Medscand, pursuant to which Ulmsten licensed Medscand to manufacture and/or market Ulmsten's patented medical device known as IVS and/or TVT;

14. All correspondence between Medscand and JnJ that refers or relates to the License and Supply Agreement and/or the Asset Purchase Agreement and any due diligence performed in relation to those agreements;

15. All financial statements, balance sheets and projections, whether certified or not, audited or not, of Medscand between the years 1995 and 2002;

16. All documents or copies of documents that Ethicon obtained from Medscand, its officers and authorized representatives during Ethicon's due diligence investigations performed in relation to the License and Supply Agreement and the Asset Purchase Agreement;

17. All motions, resolutions, minutes, authorizations, powers of attorney and/or documents evidencing or referring or relating to any corporate action by Ethicon in response to requests to enter into the License and Supply Agreement and/or the Asset Purchase Agreement;

18. The English-language Index of Mediscand's Design Control Quality Systems;

19. All reports prepared by anyone in Ethicon's Medical Affairs department that refer or relate to the License and Supply Agreement and/or the Asset Purchase Agreement;

20. All documents that constitute, refer or relate to work instructions in affect at Medscand before and/or after the execution of the License and Supply Agreement;

21. All documents that indicate the person who Ethicon made responsible for reviewing Risk Assessment/Design Control Processes and Medical Device Vigilance Reports in connection with the due diligence performed with respect to the License and Supply Agreement and/or the Asset Purchase Agreement;

22. All documents that memorialize, refer or relate to Ethicon's assessment of the product liability exposure that was associated with its purchase of the IVS and/or TVT system from Medscand and what insurance and/or litigation reserves Medscand had to indemnify itself for such exposure;

23. Any drafts of and the final report of Quality Systems concerning its due diligence investigation of Medscand in connection with the License and Supply Agreement and/or the Asset Purchase Agreement;

24. Any documents that memorialize, refer or relate to your statement in Eth.Mesh.09747933 that IVS or TVT was, "Suitable for 80% of S.U.I. incontinent patient[s];"

25. All documents that memorialize, refer or relate to any and all payments, contingent or not, made to Medscand and/or Ulmsten in connection with the License and Supply Agreement and/or the Asset Purchase Agreement;

26. All documents that memorialize, refer or relate to any assignments by Medscand to Ethicon of any supply agreement with Medscand and its contractors and suppliers;

27. All documents that memorialize, refer or relate to any due diligence performed on inventory, raw material and/or work in process that Medscand had when Ethicon and Medscand first negotiated the License and Supply Agreement, entered into the License and Supply Agreement, first negotiated the Asset Purchase Agreement and entered into the Asset Purchase Agreement;

28. All drawings of needle tip designs obtained from Medscand, which designs were intended to prevent any bladder perforation during the implantation of the IVS and/or the TVT;

29. Any documents that memorialize, refer or relate to sterilization, including but not limited to ethylene oxide sterilization of the mesh component of the IVS and/or TVT system by Ethicon, Ltd. (Scotland);

30. The Technical File and/or Design Dossier for the IVS and/or any TVT system that Ethicon compiled after it executed the Asset Purchase Agreement;

31. All Risk Analyses and/or Risk Management Reports, whether denominated as such or as a DDSA, aFMEA, pFMEA, dFMEA or otherwise, for Rigid Catheter Guide, the purchase of which was the subject in part of the Asset Purchase Agreement;

32. Medscand's SOP-04-01;

33. Medscand's Device Master Record for the IVS and/or TVT systems in their original language and as translated into any other language, including but not limited to English and/or French;

34. All documents that memorialize, refer or relate to Medscand as a certified medical device manufacturer in accordance with ISO 9001 and/or registered with the FDA;

35. All documents that memorialize, refer or relate to any labels that Medscand provided with each sale of any IVS and/or TVT unit;

36. All documents the memorialize, refer or relate to any stability studies, materials qualifications, pre-clinical data and/or clinical data that Ethicon obtained from Medscand;

37. All documents that are identified in Eth.Mesh.09748342 and in Eth.Mesh.09748347-8 under the heading, "Quality Systems" that Ethicon obtained from Medscand;

38. All documents that memorialize, refer or relate to the problem described in paragraph 5 of Eth.Mesh.09748379 and Eth.Mesh.09748381 with Ethicon, Inc. (Cornelia) and Ethicon, Ltd. (UK) as the supplier of "polypropylene mesh raw material", including but not limited to quality characteristics specified by a drawing, any root cause analysis, correction plan, and effectivity analysis; and

39. All documents that memorialize, refer or relate to Ethicon (Scotland) preparing or submitting any documents to the EMEA, Danish Notified Body or any other person, as required by Medical Device Directive 92/42/EEC or any other laws or regulations, to any other foreign government agency or regulatory authority other than the United States for the purpose of obtaining the right to legally market the IVS and/or the TVT in such foreign jurisdictions.

Yours,

Roger P. Cameron

Roger P. Cameron, Esquire
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